

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231*mk*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/757,344 01/09/01 LAYROLLE P 04148-00005

IM22/0522

JOHN P. IWANICKI  
BANNER & WITCOFF, LTD.  
28TH FLOOR  
28 STATE STREET  
BOSTON MA 02109

EXAMINER

KOLB, J

ART UNIT	PAPER NUMBER
3	1762

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/757,344	LAYROLLE ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 January 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-36 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 27-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. 09/351,518.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.  
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 27, 28, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kokubo et al '122.

Kokubo et al. teach forming a hydroxyapatite coating on metallic or organic substrates by soaking the substrate in an aqueous solution containing constituent ions of hydroxyapatite (abstract). Ions include calcium, phosphate, and magnesium (see Table 2), as required by Applicant.

3. Claims 27-28 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Li.

Li teaches a coated implant wherein the coating comprises calcium ions, phosphate ions, magnesium ions, and carbonate ions (abstract and claims). The implant substrate may be metal, ceramic, or polymer (col. 4, lines 59).

4. Claims 27-33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Leitao.

Leitao teaches a method for producing an implant article. The substrate of Leitao's invention may be made of metal, such as titanium, synthetic polymers, or ceramics (col. 2, lines 1-7). Leitao teaches coating the substrate with an amorphous calcium phosphate layer, which can be made from a combination of calcium and phosphate ions together with hydroxide, magnesium, and/or chloride ions, among others (col. 2, lines 20-25). The calcium phosphate layer may also form hydroxyapatite (col. 5, line 13). Leitao teaches pre-treatment of the substrate, prior to coating of said implant, using a chemical surface treatment, such as treatment with a strong mineral acid, or a mechanical surface treatment, such as sanding or scoring (col. 2, lines 40-50). In specific regard to claim 36, Leitao teaches pre-coating with the above coating material and then placing the implant into the body where an additional calcium phosphate layer is formed on the implant *in vivo* (col. 3, lines 1-6).

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leitao.

Leitao teaches that which is disclosed above. Additionally, Leitao teaches that the calcium phosphate coating of his invention is preferably 1-50 microns in thickness (col. 2, line 19), overlapping the ranges set forth by the Applicant. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Leitao's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shimamune et al. teach surface pre-treating a titanium implant, followed by coating with calcium phosphate.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.
9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

*jle*

Jennifer Kolb  
May 16, 2001

*M.P.B.*  
SHRIVE P. BECK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700